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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,176	02/26/2004	Steven M. Ruben	PF526C1N	3583

22195 7590 06/27/2007

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,176	RUBEN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-41,43-55 and 57* is/are rejected.

7)☒ Claim(s) *42 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 30-57 are pending in the instant application. Claims 30, 42, 44 and 56 have been amended as requested by Applicant in the Paper filed May 8, 2007.

Election/Restrictions

2. Applicant's election of Group IV in the reply filed on January 15, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of the claims embodying the subject matter of Sjogren's Syndrome in the paper filed May 8, 2007 is acknowledged. The traversal is on the ground(s) that claims 30 and 44 are Markush-type generic linking claims encompassing all of the species identified by the Office, and that there is no generic claim, and search and examination of all the groups would not entail a serious burden. This is found persuasive, and all of the claims and all of the diseases/ conditions will be searched and examined.

The requirement is still deemed proper and is therefore made FINAL.

All claims are currently under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted February, 2004 has been considered by the examiner.

Specification

4.1 The disclosure is objected to because of the following informalities: the abstract does not describe the invention.

Appropriate correction is required.

4.2 title of the invention is not descriptive. A new title is re quired that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Treatment of Sjogren's syndrome by administration of TR18 polypeptide.

Priority

5.1 Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The status of application 09/848,271 should be updated (now abandoned).

5.2 Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is entitled to the effective filing date of 04 May 2000, which is the filing date of the US Provisional application 60/201,852, which discloses that the polypeptide of SEQ ID NO:2 (TR18, also known in the art as BCMA), binds the TNF family ligand neutrokine-alpha (also known in the art as BAFF and BlyS). Should the applicant disagree with the examiner's factual determination

above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 05/04/2000, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 05/04/2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30-41, 43-55 and 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating Sjogren's Syndrome with a polypeptide that is 90% identical to a polypeptide comprising amino acids 4-44, 4-52, 4-54, 8-41, 1-54 and the extracellular domain of the TR18 receptor polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for treatment of any other autoimmune disease or condition, and additionally the specification does not provide enablement for treatment of Sjogren's Syndrome with such polypeptides that are labeled with a radioisotope, an enzyme label or a fluorescent label. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification and provisional application 60/201,852, teach that TR18 binds the ligand neutrokine-alpha (BAFF/BlyS), and were the first to disclose this. The specification also teaches that the extracellular domain or parts of the extracellular domain can be used to treat diseases that have increased levels of neutrokine-alpha, and lists Sjogren's disease as one which can be

treated with the soluble TR18 receptor (page 126, for example). Mariette et al., (ref A43) and Groom et al., (ref A42), the references submitted with the IDS filed February 26, 2004, teach that BAFF/BlyS (neutrokine-alpha) is overexpressed and correlates with autoantibodies in human Sjogren's syndrome, respectively, and that anti-BlyS/BAFF strategies, similar to anti-TNF strategies, could be useful in this disease. Therefore, given the information in the specification and that which was known in the art, the claims are enabled for a method of treating Sjogren's syndrome using a polypeptide that is 90% identical to a polypeptide comprising amino acids 4-44, 4-52, 4-54, 8-41, 1-54 and the extracellular domain of the TR18 receptor polypeptide of SEQ ID NO: 2. However, the specification and the art do not disclose whether neutrokine-alpha is overexpressed in any other autoimmune disease or condition associated with an autoimmune disease, such that the diseases or conditions in the claims could be treated with the claimed polypeptides. Absent this information, the specification does not enable treatment of Rieter's Disease, Guillain-Barre Syndrome, Hashimoto's thyroiditis, Addison's disease, biliary cirrhosis or asthma.

Additionally, claims 38, 3952 and 53 are drawn to treatment using soluble receptor polypeptide labeled with a radioisotope, an enzyme label or a fluorescent label. Such labeled polypeptides could possibly be used for diagnostic purposes, but not for therapeutic purposes. The soluble TR18 would bind the overexpressed neutrokine-alpha (BAFF/BlyS) as taught in the art (Mariette et al. and Groom et al.) and prevent the ligand from activating the receptor. However, a soluble receptor labeled with a radioisotope, for example, would cause cell death in areas where neutrokine-alpha was expressed, which would not be the desired effect of the

treatment. Fluorescent or enzyme labels would also have no therapeutic advantage and may inhibit binding of the receptor to neutrokine-alpha.

For these reasons, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Pertinent Art

7. The art considered pertinent to the present application is Marsters et al., Current Biology, Vol. 10, pages 785-788, June 16, 2000, which teaches that BlyS (neutrokine-alpha) binds to BCMA receptor (TR18 of the instant invention). This reference is of interest in being the first to disclose that TR18 binds neutrokine-alpha, however, provisional 60/201,852 filed May 4, 2000, disclosed that TR18 binds neutrokine-alpha, and is prior to that of Marsters et. al.

Conclusion

8.1 Claims 30-41, 43-55 and 57 are rejected.

8.2 Claims 42 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

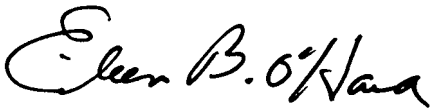
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PRIMARY EXAMINER